

AMENDMENTS TO THE CLAIMS

1-14. (Cancelled)

15. (Currently amended) A method for verifying the efficiency of sample preparation of test sample nucleic acids and the performance of nucleic acid amplification and detection practiced on a test sample after its preparation, said method comprising:

- (i) providing ~~an-a universal~~ internal control reagent selected from the group consisting of cells, parasites, cells comprising organelles, cells comprising viral particles, cells comprising parasites, ~~cells comprising bacterial cells-a sporocand any combination thereof~~, said internal control reagent having at least one internal control (IC) nucleic acid target sequence therein, wherein said internal control reagent is an internal control for the release, amplification, and detection of a nucleic acid from said test sample;
- (ii) adding mixing said internal control reagent ~~into-and~~ said test sample;
- (iii) submitting said test sample mixed with said ~~added~~-internal control reagent to a sample preparation procedure in order to release both said nucleic acid from said test sample and said IC nucleic acid target sequence from said internal control reagent; and
- (iv) submitting a product from said sample preparation procedure to amplification and detection for the amplification and detection of both said IC nucleic acid target sequence and said nucleic acid of the test sample, wherein detection of said IC nucleic acid target sequence is indicative of both efficient sample preparation and performance of nucleic acid amplification.

16. (Currently amended) The method as defined in claim 15, further comprising

- (v) comparing the amplification and detection performed in (iv) to the amplification and detection performed with a control reaction to evaluate the efficiency of the sample preparation and the performance of the nucleic acid amplification and detection practiced on said test sample and reagent.

17. (Currently amended) The method of claim 15, wherein said sample preparation procedure comprises concentrating and/or purifying cells, spores, or cells comprising organelles and/or viral particles prior to lysis.

18-19. (Cancelled)

20. (Currently amended) The method of claim 15, wherein said cells-spore is a are bacterial spores.

21. (Currently amended) The method of claim 20, wherein said cells-spore is a are *Bacillus* spores.

22. (Currently amended) The method of claim 21, wherein said cells-spore is a are *Bacillus globigii* spores.

23. (Previously presented) The method of claim 15, wherein said IC nucleic acid target sequence is on a cloning vector.

24. (Currently amended) The method of claim 2315, wherein said IC nucleic acid target sequence is on a plasmid vector.

25. (Previously presented) The method of claim 15, wherein said nucleic acid amplification method is PCR.

26. (Previously presented) The method of claim 15, wherein said IC nucleic acid target sequence is nucleic acid sequence of clinical, environmental, alimentary or human origin.

27. (Previously presented) The method of claim 15, wherein said IC nucleic acid target sequence is a nucleic acid sequence of microbial origin.

28. (Previously presented) The method of claim 15, wherein the said test sample is a sample of clinical, environmental or alimentary origin.

29. (Previously presented) The method of claim 15, wherein said test sample comprises a vaginal/anal or a nasal swab.

30. (Currently amended) The method of claim 15, wherein said sample preparation procedure comprises

(i) concentration and/or purification of cells, spores or cells comprising organelles and/or viral particles,

(ii) lysis of cells, spores, or cells comprising organelles and/or viral particles,

(iii) nucleic acid extraction,

(iv) elimination, neutralization and/or inactivation of nucleic acid testing (NAT) inhibitors, and/or

(v) nucleic acid concentration and/or purification.

31. (Cancelled)

32. (Currently amended) A method for verifying the efficiency of sample preparation of test sample nucleic acids and the performance of nucleic acid amplification and detection practiced on a test sample after its preparation, said method comprising:

- (i) providing ~~an-a universal~~ internal control reagent selected from the group consisting of a cell, a parasite, a cell comprising a ~~an~~ organelle~~spore~~, a cell comprising a viral particle, a cell comprising a parasite, a cell comprising a bacterial cell and any combination thereof, said internal control reagent having at least one internal control (IC) nucleic acid target sequence therein, wherein said internal control reagent is an internal control for the release, amplification and detection of a nucleic acid from said test sample;
- (ii) ~~adding-mixing~~ said internal control reagent ~~into-and~~ said test sample;
- (iii) submitting said test sample with said ~~added-mixed~~ internal control reagent to a nucleic acid amplification procedure in order to release both said nucleic acid from said test sample and said IC nucleic acid target sequence from said internal control reagent; and
- (iv) submitting a product from said amplification procedure to further amplification or detection for the amplification or detection of both said IC nucleic acid target sequence and said nucleic acid of the test sample, wherein detection of said IC nucleic acid target sequence is indicative of both efficient sample preparation and performance of nucleic acid amplification.

33. (Currently amended) The method of claim 46-32, wherein said sample preparation procedure comprises concentrating and/or purifying cells, ~~spores~~, or cells comprising organelles and/or viral particles prior to lysis.

34-35. (Cancelled)

36. (Currently amended) The method of claim 4632, wherein said ~~cells-spore is are-a~~ bacterial spores.

37. (Currently amended) The method of claim 36, wherein said ~~cells-spore are-is a~~ *Bacillus* spores.

38. (Currently amended) The method of claim 37, wherein said ~~cells-spore are-is a~~ *Bacillus globigii* spores.

39. (Currently amended) The method of claim 4632, wherein said IC nucleic acid target sequence is on a cloning vector.

40. (Currently amended) The method of claim 3932, wherein said IC nucleic acid target sequence is on a plasmid vector.

41. (Currently amended) The method of claim 4632, wherein said nucleic acid amplification method is PCR.

42. (Currently amended) The method of claim 4632, wherein said IC nucleic acid target sequence is nucleic acid sequence of clinical, environmental, alimentary or human origin.

43. (Currently amended) The method of claim 4632, wherein said IC nucleic acid target sequence is a nucleic acid sequence of microbial origin.

44. (Currently amended) The method of claim 16, 32 wherein the said test sample is a sample of clinical, environmental or alimentary origin.

45. (Currently amended) The method of claim 4632, wherein said test sample comprises a vaginal/anal or a nasal swab.

46. (Currently amended) The method of claim 4632, wherein said sample preparation method comprises

(i) concentration and/or purification of cells, spores, or cells comprising organelles and/or viral particles,

(ii) lysis of cells, organelles or cells comprising organelles and/or viral particles,

(iii) nucleic acid extraction,

(iv) elimination, neutralization and/or inactivation of nucleic acid testing (NAT) inhibitors, and/or

(v) nucleic acid concentration and/or purification.

47. (New) The method of claim 15, wherein said amplification reaction comprises contacting said product from said sample preparation procedure with a primer pair comprising SEQ ID NO:7 and SEQ ID NO:8.

48. (New) The method of claim 32, wherein said amplification reaction comprises contacting said product from said sample preparation procedure with a primer pair comprising SEQ ID NO:7 and SEQ ID NO:8.

49. (New) The method of claim 15, wherein said spore is purified prior to mixing with said test sample.

50. (New) The method of claim 32, wherein said spore is purified prior to mixing with said test sample.

51. (New) The method of claim 49, wherein said purification eliminates vegetative cells from said internal control reagent.

52. (New) The method of claim 40, wherein said purification eliminates vegetative cells from said internal control reagent.

53. (New) The method of claim 15, wherein said internal control reagent comprises about 500 spores.

52. (New) The method of claim 32, wherein said internal control reagent comprises about 500 spores.

53. (New) The method of claim 15, wherein said amplification reaction comprises contacting said product from said sample preparation procedure with a first primer pair designed to amplify said internal control nucleic acid target, and a second primer pair designed to amplify said nucleic acid from said test sample, wherein the first and second primer pairs are different.

54. (New) The method of claim 32, wherein said amplification reaction comprises contacting said product from said sample preparation procedure with a first primer pair designed to amplify said internal control nucleic acid target, and a second primer pair designed to amplify said nucleic acid from said test sample, wherein the first and second primer pairs are different.

55. (New) The method of claim 53, wherein the amplification product of said second primer pair is shorter than the amplification product of said first primer pair.

56. (New) The method of claim 54, wherein the amplification product of said second primer pair is shorter than the amplification product of said first primer pair.